

Product Biomonitoring and Responsible Reporting

doi:10.1289/ehp.1003355

In this issue of *Environmental Health Perspectives* (EHP), Schecter et al. (2011) report levels of polybrominated diphenyl ether (PBDE) flame retardants in butter purchased from retail stores. Although the investigators found prevalent levels of PBDEs in butter, they report that one sample had inordinately high levels of octa-, nona-, and deca-BDE congeners, likely from its highly contaminated wrapping paper.

The safety of PBDEs has come into question (DiGangi et al. 2010). Chemical companies have voluntarily phased out penta- and octa-BDEs in the United States and have agreed to do so for deca-BDE production, and some states have banned PBDE use in consumer products such as mattresses and electronics (U.S. Environmental Protection Agency 2007, 2010). The presence of these chemicals in food products has not been addressed explicitly in legislation or regulations in the United States.

Given the lack of clear regulatory guidance and the question of risk from high levels of PBDEs in food products, it is legitimate to ask: should investigators in these types of "product biomonitoring" studies, when confronted with startling results from any potentially risky chemical, report their results to the manufacturer or to any regulatory agency prior to publication? Should the investigators identify specific brand name products and their manufacturers in their manuscript? More important, would the public want to know such results?

In a study of clinical trial subjects in brain imaging studies, Kirschen et al. (2006) found that at least 91% of the subjects, depending on the setting, wanted incidental findings to be disclosed to them, regardless of their clinical significance. In a workshop at which investigators discussed incidental findings, Illes (2006) found that most of the participants believed that research protocols should provide for disclosure of incidental findings. In environmental exposure studies there is no clear consensus on reporting individual data (Morello-Frosch et al. 2009), but Brody et al. (2007) found that an overwhelming majority of subjects (97%) were interested in knowing their personal results, regardless of the limited or absence of scientific information related to the health risks of that data.

But the study by Schecter et al. (2011) is not a clinical trial, nor does the study include human subjects with measurements of internal exposures. On the other hand, the butter obtained for this study would otherwise have been purchased and consumed; additional lots of butter, similarly contaminated, may be awaiting purchase or may have already been consumed. In cases such as this, do clinical trial and environmental exposure reporting recommendations apply, including any ethical requirements to notify subjects of incidental findings? And who are the "subjects" in such product biomonitoring studies?

A secondary question relates to the planning of such research: Should product biomonitoring protocols plan for reporting of results? Should this issue be addressed in a prestudy protocol, perhaps subject to vetting by an institutional review board (IRB)-like committee with data safety monitoring board (DSMB) oversight? Clearly, product biomonitoring studies without human subjects fall outside the realm of current IRB and DSMB jurisdiction. Given that IRBs and DSMBs are assembled to determine the risks to study participants, product contaminants of questionable risk may be too ambiguous for clear direction. These oversight bodies may thus be placed in a difficult position of interpreting the science behind a particular contaminant in addition to advising the conduct of a research study. Regardless, it would be appropriate for investigators who conduct such studies to explicitly identify in their protocol procedures for handling and reporting results, both expected and unexpected. This may have implications on where and how data will be submitted for publication and use, but will likely help guide



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the investigators when surprising, incidental findings arise. Hernick et al. (2011) recently described their experience communicating unexpected biomarker results in a population of girls; their model may provide guidance for future research endeavors.

Some people may fear that making product biomonitoring data public might generate alarm or panic among consumers, but research indicates this is unlikely (Altman et al. 2008). Schecter's research team has already published data on PBDEs in composite food samples (Schecter et al. 2010a) and on bisphenol A in identified, brand-name food products (Schecter et al. 2010b) without apparent widespread panic among the public. In addition, the Food and Drug Administration (FDA) conducts regular market basket studies as part of its Total Diet Study (TDS) (FDA 2010). The TDS does not measure PBDEs (FDA 2009a), but it does measure other chemicals of concern in common consumer food products; results are made public (FDA 2009b), but the FDA does not identify specific brand names of sampled products or their manufacturers in their public data reports. The FDA does, however, pursue regulatory action if warranted by TDS results (Egan 2002).

Given the preferences of subjects in environmental exposure studies and the practice of the FDA in the TDS, it is clearly reasonable to make results of product biomonitoring studies public. But should a specific brand-name product or manufacturer be identified? One consideration is whether the product sampled in a study is representative of the totality of that product, or merely a small, inadvertently contaminated production lot. It would be unfair for a single sample to tarnish the reputation of a product without additional data. In addition, the specter of litigation looms over such decisions (Ledford 2008). Reporting of results tied to a specific product or manufacturer may result in an injunction against publication, accompanied by a subpoena for original data or litigation to repeat studies for validation purposes prior to release of results. The journal publishing the paper may also find itself a party to such litigation.

Schecter et al. (2011) indicate that they informed the butter manufacturer of their results. This was clearly a responsible act on their part. Making results public by publishing this important information in an open access journal such as *EHP* is also appropriate. Product manufacturers should act, of course, in the best interest of the public's health. The issue of results notification in product biomonitoring studies is worthy of more detailed examination, and consensus among researchers and journals should be a priority.

I gratefully acknowledge J. Brody for her assistance with background information for this editorial.

This editorial does not reflect policy of the National Institute of Environmental Health Sciences of the National Institutes of Health.

The author declares that he has no actual or potential competing financial interests.

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REFERENCES

- Altman RG, Morello-Frosch R, Brody JG, Rudel R, Brown P, Averick M. 2008. Pollution comes home and gets personal: women's experience of household chemical exposure. *J Health Soc Behav* 49(4):417–435.
- Brody JG, Morello-Frosch R, Brown P, Rudel RA, Altman RG, Frye M, et al. 2007. Improving disclosure and consent: "is it safe?": new ethics for reporting personal exposures to environmental chemicals. *Am J Public Health* 97(9):1547–1554.
- DiGangi J, Blum A, Bergman Å, de Wit CA, Lucas D, Mortimer D, et al. 2010. San Antonio Statement on brominated and chlorinated flame retardants. *Environ Health Perspect* 118:A516–A518; doi:10.1289/ehp.1003089 [Online 28 October 2010].
- Egan K. 2002. FDA's Total Diet Study: Monitoring U.S. Food Supply Safety. *Food Safety Magazine* June/July. Available: <http://www.fda.gov/Food/FoodSafety/FoodContaminantsAdulteration/TotalDietStudy/ucm186140.htm> [accessed 9 November 2010].
- Food and Drug Administration. 2009a. Total Diet Study – Analytes and Analytical Methods. Available: <http://www.fda.gov/Food/FoodSafety/FoodContaminantsAdulteration/TotalDietStudy/ucm184646.htm> [accessed 9 November 2010].
- Food and Drug Administration. 2009b. Total Diet Study – Analytical Results. Available: <http://www.fda.gov/Food/FoodSafety/FoodContaminantsAdulteration/TotalDietStudy/ucm184293.htm> [accessed 9 November 2010].
- Food and Drug Administration. 2010. Total Diet Study. Available: <http://www.fda.gov/Food/FoodSafety/FoodContaminantsAdulteration/TotalDietStudy/default.htm> [accessed 9 November 2010].
- Hernick AD, Brown MK, Pinney SM, Biro FM, Ball KM, Bornschein RL. 2011. Sharing unexpected biomarker results with study participants. *Environ Health Perspect* 119:1–5; doi:10.1289/ehp.1001988 [Online 29 September 2010].
- Illes J, Kirschen MP, Edwards E, Stanford LR, Bandettini P, Cho MK, et al. 2006. Ethics: incidental findings in brain imaging research. *Science* 311:783–784.
- Kirschen MP, Jaworska A, Illes J. 2006. Subjects' expectations in neuroimaging research. *J Magn Reson Imaging* 23(2):205–209; doi:10.1002/jmri.20499 [Online 13 January 2006].
- Ledford H. 2008. Company sues researcher over unfavourable review: Biopure says meta-analysis harmed its product. *Nature*; doi:10.1038/news.2008.1219 [Online 11 November 2008].
- Morello-Frosch R, Brody JG, Brown P, Altman RG, Rudel RA, Pérez C. 2009. Toxic ignorance and right-to-know in biomonitoring results communication: a survey of scientists and study participants. *Environ Health* 2009, 8:6; doi:10.1186/1476-069X-8-6 [Online 28 February 2009].
- Schechter A, Haffner D, Colacino J, Patel K, Pöpke O, Opel M, et al. 2010a. Polybrominated diphenyl ethers (PBDEs) and hexabromocyclodecane (HBCD) in composite U.S. food samples. *Environ Health Perspect* 118:357–362; doi:10.1289/ehp.0901345 [Online 28 October 2009].
- Schechter A, Malik N, Haffner D, Smith S, Harris TR, Paepke O, Birnbaum L. 2010b. Bisphenol A (BPA) in U.S. Food. *Environ Sci Technol* 44(24):9425–9430; doi: 10.1021/es102785d [Online 1 November 2010].
- Schechter A, Smith S, Colacino J, Malik N, Opel M, Paepke O, et al. 2011. Contamination of U.S. butter with PBDEs from wrapping paper. *Environ Health Perspect* 119:151–154; doi:10.1289/ehp.1002604 [Online 7 December 2010].
- U.S. Environmental Protection Agency. 2007. Polybrominated Diphenylethers (PBDEs) Significant New Use Rule (SNUR) Questions and Answers. Available: <http://www.epa.gov/oppt/pbde/pubs/qanda.htm> [accessed 9 November 2010].
- U.S. Environmental Protection Agency. 2010. DecaBDE Phase-out Initiative. Available: <http://www.epa.gov/oppt/existingchemicals/pubs/actionplans/deccadbe.html> [accessed 9 November 2010].

Editor's Note

2010 Reviewers of the Year

Like all peer-reviewed journals, *EHP* relies on the diligence and integrity of experts to help determine the quality and impact of papers submitted for possible publication. In 2010 *EHP* received over 1,450 papers, and about 550 of those papers were sent by our Associate Editors to at least two anonymous peer reviewers for evaluation. *EHP* published 268 papers in 12 issues during 2010, and the journal is very grateful for the time and effort of the more than 1,000 reviewers who assisted us last year. A list of those reviewers is available on the journal's website (<http://ehponline.org/article/info:doi/10.1289/ehp.119-a59>).

In this issue, *EHP* recognizes its top 12 Reviewers of the Year. These are individuals who reviewed at least five papers during the year and received excellent ratings for the timeliness and quality of their reviews by the Associate Editor who handled the peer-review process. They are Carol Angle, Adrian Barnett, Joe Braun, Jane Clougherty, Adrienne Ettinger, Matthew Longnecker, John Meeker, Sumi Mehta, David Savitz, Leonardo Trasande, Roberta White, and Judith Zelikoff. We congratulate these reviewers and thank the hundreds of others who contributed to the success of *EHP* in 2010.



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Jane Clougherty



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